From: Gwinn, Maureen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4BDC5237A5C440A7B664518E23EB5647-GWINN, MAUREEN]

**Sent**: 11/14/2019 2:34:58 AM

To: D'Amico, Louis [DAmico.Louis@epa.gov]
CC: Thomas, Russell [Thomas.Russell@epa.gov]

Subject: Need some feedback - Report to Congress on Alternative Toxicity Testing

Attachments: Alternative Animal Testing for OCFO\_Review 11132019.docx

Lou – can you look at the remaining comments in the attached, some of which are highlighted below - are these all necessary to moving this forward and/or do you have recommendations for some of them, particularly related to EPA definitions, need for proof for statements that seem to not need them?

# Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Thank you.

Maureen

Maureen Gwinn BCTD/CCTE/ORD/EPA

t(919)541-3794

N Ex. 6 Personal Privacy (PP)

From: Gwinn, Maureen

Sent: Thursday, September 26, 2019 11:41 AM

To: Scarano, Louis <Scarano.Louis@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Cowden, John

<Cowden.John@epa.gov>; Wetmore, Barbara <wetmore.barbara@epa.gov>; Schappelle, Seema

<Schappelle.Seema@epa.gov>; Lambert, Jason <Lambert.Jason@epa.gov>; Hines, Ronald <Hines.Ronald@epa.gov>

Cc: Thomas, Russell < Thomas. Russell@epa.gov>

Subject: One step closer...Report to Congress on Alternative Toxicity Testing

One step closer! Ex. 5 Deliberative Process (DP)

I will keep you all posted.

Anna.

### Ex. 5 Deliberative Process (DP)

#### Ex. 5 Deliberative Process (DP)

Thanks!

Maureen

Maureen Gwinn ORD/EPA t(202)564-4621 m(Ex. 6 Personal Privacy (PP)

From: Muellerleile, Caryn < Muellerleile. Caryn@epa.gov>

Sent: Thursday, September 26, 2019 10:50 AM

**To:** Gwinn, Maureen <gwinn.maureen@epa.gov>; D'Amico, Louis <<u>DAmico.Louis@epa.gov</u>>; Burden, Susan <Burden.Susan@epa.gov>

Cc: Manibusan, Mary < Manibusan. Mary@epa.gov>

Subject: FW: OP Review of Report to Congress on Alternative Toxicity Testing - comments due 9/28

Greetings,

OP has approved this Report to move forward. Let me know if you need additional assistance.

Caryn Muellerleile
Regulatory Management Division
Office of Policy
US Environmental Protection Agency
1200 Pennsylvania Ave NW (1803A)
Washington, DC 20460
(202) 564-2855
muellerleile.caryn@epa.gov

From: Gwinn, Maureen <gwinn.maureen@epa.gov>

Sent: Saturday, September 14, 2019 2:55 PM

To: Muellerleile, Caryn < Muellerleile. Caryn@epa.gov >; Burden, Susan < Burden. Susan@epa.gov > Cc: Manibusan, Mary < Manibusan. Mary@epa.gov >; D'Amico, Louis < DAmico. Louis@epa.gov > Subject: RE: OP Review of Report to Congress on Alternative Toxicity Testing - comments due 9/28

Caryn,

Please find attached the updated Report to Congress on Alternative Toxicity Testing for OP review. As discussed, we included a citation to the recently released Administrator's memo, and updated any outdated links or information. I have left those revisions in track changes to make it easier to see what was updated.

Please review and send me any comments by 9/28. If more time is needed, please let me know

x. 5 Deliberative Process (DP

## Ex. 5 Deliberative Process (DP)

Thank you,

Maureen

Maureen Gwinn ORD/EPA t(202)564-4621 m Ex. 6 Personal Privacy (PP)

From: Muellerleile, Caryn < Muellerleile. Caryn@epa.gov>

**Sent:** Monday, August 26, 2019 3:02 PM

To: Gwinn, Maureen <gwinn.maureen@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>

Cc: Manibusan, Mary < Manibusan. Mary@epa.gov>

Subject: FW: OP Review of Report to Congress on Alternative Toxicity Testing

With attachments!

From: Gwinn, Maureen <gwinn.maureen@epa.gov>

Sent: Wednesday, May 08, 2019 12:42 PM

To: Muellerleile, Caryn < Muellerleile. Caryn@epa.gov>

Cc: Burden, Susan < Burden. Susan@epa.gov>

Subject: OP Review of Report to Congress on Alternative Toxicity Testing

Hi Caryn,

Thanks for taking the time to talk to me today and looking into options for the OP review of this document. Please find attached the latest draft of the Report to Congress on Alternatively Toxicity Testing Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

The detailed request from appropriations is included at the end of the report, but also pasted below for ease of review. This was a request from FY18 and repeated in FY19, but no due date was included. The pdf attached is the report mentioned in the Congressional language below.

Thank you for spearheading the OP review. I generally start with a 2-week time frame for review, but can be very flexible if you need more time. Please let me know if you need additional time for review or if you have any questions,

#### Maureen

Maureen R. Gwinn, PhD DABT ATS
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t(202)564-4621 f(202)565-2430 m Ex. 6 Personal Privacy (PP)

# Congressional Reporting Requirement Origins

Under the Department of the Interior, Environment and Related Agencies Appropriations Act of 2018, the Environmental Protection Agency is recommended to follow the language set forth in House Report 115-238 unless otherwise noted in the Act. The Act also emphasizes that EPA undertake certain activities such as writing a report on Alternative Toxicity Testing. The language in both the Appropriations Act and the House Report is below:

Alternatives Testing as stated in the Appropriations Act of 2018. The Agency is directed to follow the guidance contained under this heading in House Report 115-238 and to also include in its report to the Committees information and analysis related to potential barriers or limitations on the use of alternative test methods and to ensure that any future plans address such barriers or limitations, particularly as they relate to susceptible populations.

Alternatives Testing as Stated in House Report 115-238. The Committee commends EPA for developing new scientific methods, removing barriers, and fostering cooperation in implementing the toxicity testing agenda included in the 2007 National Research Council (NRC) report, "Toxicity Testing in the 21st Century." The Committee is also aware that the Agency is incorporating an alternative scientific approach to screen chemicals within its Endocrine Disruptor Screening Program as called for in fiscal year 2015 (House Report 113–551: <a href="https://www.congress.gov/113/crpt/hrpt551/CRPT-113hrpt551.pdf">https://www.congress.gov/113/crpt/hrpt551/CRPT-113hrpt551.pdf</a>). The Committee is interested in how the Agency is implementing the same approach in all of its programs that involve toxicity testing and recommends that the Agency submit to the Committee a report that outlines (1) progress to date to research, develop, validate and translate innovative non-animal chemical testing methods that characterize toxicity pathways, (2) efforts to coordinate this across Federal agencies, and (3) future plans to continue to implement the toxicity testing vision outlined in the January 2017 NAS report, "Using 21st Century Science to Improve Risk-Related Evaluations" on all Agency programs that involve toxicity testing.